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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,757	02/11/2004	Michel Pairet	1/1174-1-C1	3466

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,757	PAIRET ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,15-39 and 63-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,15-39 and 63-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/086,145.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11 February 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-10, 15-39, and 63-66 are pending in the application, in response to the restriction requirement submitted on May 21, 2007. Claims 2, 11-14 and 40-62 have been cancelled in a Preliminary Amendment filed on February 11, 2004. Accordingly, claims 1, 3-10, 15-39, and 63-66 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group II, namely claims 1-39, 49-58 and 61-66, in the reply filed on August 21, 2007 is acknowledged. The traversal is on the ground(s) that the product claims in Groups I and II are directed to inhalable powders of the same active ingredients but only differ as to whether or not they contain a propellant.

Applicants' arguments were not found persuasive because the search for propellants would represent a search burden to the Examiner since each propellant is structurally distinct from one another.

Additionally, because many products can be used with the process of Group III and thus the search for the products of Group II will not necessarily yield the process of Group III. Furthermore, if the product claims of Group I are found allowable, then the process claims of Group III will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai*.

It is noted that claims 2, 11-14 and 40-62 have been cancelled in a Preliminary Amendment filed on February 11, 2004. Election was made with traverse in the reply filed on August 21, 2007.

3. Applicants' election with traverse of: (1) tiotripium bromide as the anticholinergic; (2) ciclesonide as the steroid; and (3) lactose as the excipient, in the reply filed on August 21, 2007 is acknowledged. The traversal is on the ground(s) that all of the claims fall within the same class and subclass and thus there should be no undue burden in searching all of the claims at once.

Applicants' arguments were not found persuasive. The Examiner maintains and argues that there is a search burden for anticholinergics because each anticholinergic is structurally distinct from one another. The Examiner also maintains and argues that there is a search burden for steroids because each steroid is structurally distinct from one another. The Examiner further maintains and argues that there is a search burden for excipients because each excipient is structurally distinct from one another.

It is noted that claims 2, 11-14 and 40-62 have been cancelled in a Preliminary Amendment filed on February 11, 2004. Election was made with traverse in the reply filed on August 21, 2007.

Accordingly, claims 1, 3-10, 15-39, and 63-66 are examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Claims 1, 3-10, 15-39, and 63-66 are directed to an inhalable powder pharmaceutical composition and thus intended use is not given any patentable weight.

Information Disclosure Statement

The Information Disclosure Statement submitted on February 11, 2004, is acknowledged.

Specification

4. The use of the trademarks Handihaler® and Respimat® have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-10, 15-39, and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magee et al. (US 2002/0111495).

Magee et al. teach pharmaceutical compositions comprising tiotropium bromide and ciclesonide (page 34, paragraph [0218]). The pharmaceutical composition further contains lactose (page 102, paragraph [0697]). The pharmaceutical composition is prepared as a dry powder for delivery by inhalation (page 103, paragraph [0706]; and page 104, paragraph [0709]). The pharmaceutical composition may be contained in a solid implant (page 104, paragraph [0708]).

Regarding the weight ratio of the anticholinergic to the steroid as recited in instant claims 9 and 10, although Magee et al. does not teach the weights of tiotropium bromide and ciclesonide, they do teach pharmaceutical compositions comprising tiotropium bromide and ciclesonide (page 34, paragraph [0218]), which closely meets the weight ratio of the anticholinergic to the steroid set forth in instant claims 9 and 10. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of tiotropium bromide and ciclesonide provided in a composition, according to the guidance set forth in Magee et al., to provide a composition having desired tiotropium bromide and ciclesonide content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the maximum average particle size as recited in instant claims 15-22, although Magee et al. do not teach the maximum average particle size of tiotropium bromide and ciclesonide, they do teach the pharmaceutical composition of tiotropium bromide and ciclesonide is prepared as a dry powder (page 104, paragraph [0709]), which closely meets the percentage

weight of the antiviral lipid component set forth in instant claims 15-22. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the maximum average particle size of tiotropium bromide and ciclesonide provided in a composition, according to the guidance set forth in Magee et al., to provide a composition having desired maximum average particle size of tiotropium bromide and ciclesonide. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding a capsule containing the inhalable powder composition as recited in claims 23-38, Magee et al. teach the pharmaceutical composition of tiotropium bromide and ciclesonide may be contained in a solid implant (page 104, paragraph [0708]). It would be obvious to one skilled in the art that the solid implant may be a capsule.

Regarding kits and direction for using the kit as recited in claims 63-66, it is noted that one "need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate". See *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994). "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art". *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983), "Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and

unobvious functional relationship between the printed matter and the substrate". Accordingly, adding instructions for using a kit does not distinguish the instant claims from the prior art.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 Drechsel et al. (US 6,890,517).

Claim 1 of Drechsel et al. is directed to a liquid pharmaceutical composition comprising tiotropium salt, a steroid, and pharmacologically acceptable adjuvants and additives.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claim of Drechsel et al. would be obvious to the instant claim 1 because even though Drechsel et al. teach a liquid composition, a liquid composition is nonetheless a pharmaceutical composition. Furthermore, the claim of Drechsel et al. would be obvious over the instant claim 1 because tiotropium bromide is a tiotropium salt, ciclesonide is a steroid, and lactose may be considered a pharmacologically acceptable adjuvant or additive.

2. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Pairet et al. (11/006,940).

Claim 1 of Pairet et al. is directed to a pharmaceutical composition comprising an anticholinergic, a steroid, and optionally a pharmaceutically acceptable excipient.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claim of Pairet et al. is obvious over the instant claim 1 because tiotropium bromide is an anticholinergic, ciclesonide is a steroid, and lactose can be considered a pharmaceutically acceptable excipient.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

3. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Drechsel et al. (11/068,134).

Claim 1 of Drechsel et al. is directed to a liquid pharmaceutical composition comprising tiotropium bromide, a steroid, and pharmacologically acceptable adjuvants and additives.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claim of Dreshcel et al. would be obvious to the instant claim 1 because even though Drechsel et al. teach a liquid composition, a liquid composition is nonetheless a pharmaceutical composition. Furthermore, the claim of Dreshcel et al. would be obvious to the instant claim 1 because ciclesonide is a steroid and lactose may be considered a pharmacologically acceptable adjuvant or additive.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

4. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application Konetzki et al. (11/109,094).

Claims 1-2 of Konetzki et al. are directed to a pharmaceutical composition comprising an anticholinergic and a steroid.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claims of Konetzki et al. would be obvious over the instant claim 1 because tiotropium bromide is an anticholinergic, ciclesonide is a steroid, and a pharmaceutical composition would be expected to contain excipients such as lactose.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

5. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application Schmelzer et al. (11/169,876).

Claims 1-3 of Schmelzer et al. are directed to an aerosol containing suspension comprising of an aerosol suspension comprising a combination of anticholinergics and steroids.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claims of Schmelzer et al. would be obvious over the instant claim 1 because even though Schmelzer et al. teach an aerosol containing suspension, an aerosol suspension is nonetheless a pharmaceutical composition. Furthermore, the claim of Schmelzer et al. would be obvious to the instant claim 1 because tiotropium bromide is an anticholinergic, ciclesonide is a steroid, and a pharmaceutical composition would be expected to contain excipients such as lactose.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

6. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application Meade et al. (11/267,354).

Claims 1-2 of Meade et al. are directed to a pharmacological composition of an anticholinergic, a steroid, a betamimetic, and a pharmaceutically acceptable excipient or carrier.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claims of Meade et al. would be obvious over the instant claim 1 because the open language of "comprising" in the instant claim allows for the instant pharmaceutical composition to contain a betamimetic. Furthermore, the claim of Meade et al. would be obvious to the instant claim 1 because tiotropium bromide is an anticholinergic, ciclesonide is a steroid, and lactose may be considered a pharmaceutically acceptable excipient or carrier.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

7. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18 and 71-72 of copending Application Pop et al. (11/424,244).

Claims 18 and 71-72 of Pop et al. are directed to a pharmaceutical composition comprising tiotropium salt and a steroid.

The instant claim 1 is directed to a pharmaceutical composition of tiotropium bromide as an anticholinergic, ciclesonide as a steroid, and lactose as an excipient.

The claims of Pop et al. would be obvious over the instant claim 1 because bromide is well known in the art as a salt and thus tiotropium bromide may be a tiotropium salt. Furthermore, the claim of Pop et al. would be obvious to the instant claim 1 because ciclesonide is a steroid and a pharmaceutical composition is expected to contain pharmaceutically acceptable excipients such as lactose.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHENGJUN WANG

ckh